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CDC Advisers Tout RSV Vaccines as FDA Admits Shots Linked to Rare Immune Disorder in Older Adults

The Centers for Disease Control and Prevention's vaccine advisory committee met last week to discuss vaccines and treatments for a wide variety of illnesses, including respiratory syncytial virus (RSV), monkeypox (renamed mpox) and COVID-19, amid new reports of Guillain-Barré syndrome cases in elderly who received the RSV vaccine.

By Michael Nevradakis, Ph.D.

24

RSV
RESPIRATORY SYNCYTIAL VIRUS
VACCINE
SARS-COV-2
CORONAVIRUS
COVID-19
VACCINE
FLU
VACCINE

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In a meeting spanning three days, the Centers for Disease Control and Prevention's (CDC) vaccine advisory committee last week convened in Atlanta to discuss data and recommendations pertaining to new and updated vaccines, and updates for existing vaccines covering a wide range of diseases and conditions.

The Advisory Committee on Immunization Practices (ACIP), which meets three times a year "to review scientific data and vote on vaccine recommendations," discussed vaccines and treatments for mpox (monkeypox), influenza, polio, pediatric and adult RSV, chikungunya, dengue, varicella (chicken pox), COVID-19 bivalent and pneumococcal and meningococcal vaccines.

Here's a roundup of key topics addressed during last week's meetings.

New RSV vaccines — Are they safe? Does anyone need them?

The ACIP "weighed recommendations for two respiratory syncytial virus (RSV) vaccines for older adults and pregnant women and a monoclonal antibody for babies and toddlers," USA Today reported.

Although RSV is not a newly identified virus, Dr. Meryl Nass, a member of the Children's Health Defense scientific advisory committee who live-blogged the meetings, said we've "just started hearing about it" because "the industry developed three new RSV products."

According to Nass, the U.S. Food and Drug Administration (FDA) is considering the products even though committee members admitted, "We don't actually know how much of a problem RSV is, especially in the elderly."

The vaccines also aren't without safety concerns, especially those targeting the elderly population.

The two candidates for elderly adults are Pfizer's Abrysvo, a bivalent recombinant protein subunit vaccine, and GSK's Arexvy, a recombinant adjuvanted vaccine, according to Pharma Intelligence.

Two people in their 60s out of about 20,000 people who received Pfizer's RSV shot were diagnosed with Guillain-Barré syndrome, a rare disorder in which the body's immune system attacks its nerves, the FDA last week acknowledged.

Pfizer attributes the incidences of Guillain-Barré syndrome to other causes, according to the same FDA document.

One severe case of Guillain-Barré syndrome was attributed to the GSK candidate by the investigator and FDA, Pharma Intelligence reported.

One death was recorded during a GSK trial, Study 007, attributed to acute disseminated encephalomyelitis 22 days after vaccination, "considered by both the study investigator and FDA to potentially be related to the vaccine," according to Pharma Intelligence.

At least one case of inflammatory neuropathy for each of the two candidate vaccines was also identified during trials, Pharma Intelligence reported.

According to USA Today, both vaccines were shown to be effective in clinical trials, although, "The big debate surrounding these vaccines was whether to recommend them for adults 60 and older, or 65 and older."

USA Today reported:

> "Some panel experts argued the vaccines should be recommended to an older population because the risk for severe illness, hospitalization and death tends to increase with age.
>
> "But others argued the vaccines should be recommended for people 60 and older to narrow gaps in health equity, as adults from racially diverse and low-income communities tend to suffer the worst outcomes of RSV at earlier ages."

GSK's candidate vaccine for the elderly includes a novel adjuvant, AS01, which was discussed during the ACIP proceedings and which Nass said, "can overstimulate the immune system, which is why it is only used for the elderly or immunocompromised."

"We can assume this adjuvant will cause higher acute and chronic side effects, and is only being used because the vaccine will be used in the elderly who have fewer adverse reactions due to less immune stimulation," Nass wrote in her live blog.

The ACIP is expected to act quickly on the vaccine candidates for elderly adults, meeting tomorrow and Wednesday "to take separate safety and efficacy votes" on Abrysvo and Arexvy.

"The FDA's briefing documents released 24 February don't give any indication the two vaccines will have a difficult time getting a positive recommendation from the committee and thus a full approval by the agency," Pharma Intelligence reported.

But it's unclear whether the FDA will approve the vaccines for people age 60 and older, or for those 65 and older.

According to Nass, the data presented showed that for those over age 65, "over 1,000 vaccinations [are] needed to prevent one hospitalization, and over 21,000 to prevent one death."

Nass also referred to a recently published study co-authored by Dr. Anthony Fauci, which concludes, "none of the predominantly mucosal respiratory viruses have ever been effectively controlled by vaccines."

"Fauci says we cannot develop a good flu, RSV or COVID vaccine using current platforms," Nass said.

FDA to vote in October on Pfizer's RSV vaccine for pregnant women

The committee also discussed Pfizer's RSV candidate for pregnant women, RSVpreF. According to USA Today, "The FDA announced it has agreed to review Pfizer's vaccine candidate, RSVpreF, for approval and set an action date for August 2023. If approved, the vaccine would be for pregnant people to help protect against RSV severe disease in infants from birth through 6 months."

Pfizer told the committee that pregnant women who received the vaccine during trials "experienced moderate to mild side effects like redness, swelling and some pain at the injection site, fatigue; and headache, nausea, muscle or joint pain, vomiting and diarrhea."

According to USA Today, "A working group for Pfizer's maternal vaccine won't make suggested recommendations until June. In the meantime, panel experts raised questions regarding breastfeeding and limited data," including "how breastfeeding played a role in transferring RSV immunity to the infant" and more data "specific to pregnancy and birth."

Nass questioned the "high efficacy numbers" for the vaccine, noting that efficacy was shown to drop precipitously after several months, indicating the efficacy figures were "probably optimistic."

The FDA will vote on this vaccine in October.

Sanofi-AstraZeneca vaccine for newborns would 'prevent RSV lower respiratory tract disease'

ACIP also reviewed nirsevimab, a monoclonal antibody developed by Sanofi and AstraZeneca to "prevent RSV lower respiratory tract disease in newborns and infants entering or during their first RSV season," USA Today reported.

According to USA Today, the FDA accepted nirsevimab to review for approval in January. If approved, it would be the second monoclonal antibody on the market for infants. The other option — palivizumab — is recommended only for high-risk infants who were born severely premature at 29 weeks or earlier.

Clinical trial data reviewed by ACIP claimed nirsevimab "was about 80% effective against medically attended RSV lower respiratory tract infections in infants born at 35 weeks or later" and "reduced the incidence of infections by 70% in healthy preterm infants born between 29 and 35 weeks compared to the placebo," said USA Today.

The same research recommended nirsevimab for "all babies at birth if born during October through March," within eight months of their first RSV season, "preferably during their two-, four- or six-month wellness visit" for babies born between April and September, and for "high-risk babies entering their second RSV season."

However, USA Today reported that ACIP had some reservations about calling nirsevimab a vaccine, although "panel experts think it should get vaccine perks."

"If approved by the FDA later this year, the CDC panel will have an official vote on recommendations followed by the CDC director's approval," USA Today added.

"Efficacy assumption showed 30% at 3 months — but they threw 80% efficacy into their model for the first few months," wrote Nass on her live blog. "I cannot take this seriously. Without high quality data to plug in, this is an intellectual circle jerk — especially since side effects and their quantitative effect have yet to be mentioned."

Nass also noted that it was discussed during the proceedings that nirsevimab "only helps lung infections, not upper respiratory infection."

"It looks like the pregnancy vaccine and the newborn monoclonal will definitely be a go," Nass said, "as these people have never seen a vaccine they didn't like. And there was no useful safety data nor efficacy data presented. But there was a whole lotta modeling going on."

Pharma Intelligence reported that ACIP members admitted they are "uncertain how much RSV there is" and what the epidemiology of RSV will be "after the disruption of the COVID-19 pandemic."

Members also raised concerns about "substantial uncertainty" of the "net societal costs of RSV vaccination."

ACIP considers replacing original COVID primary series with bivalent vaccines

COVID-19 vaccines were also on the ACIP agenda last week.

According to Pharma Intelligence, ACIP supports replacing the monovalent formulation of the mRNA COVID-19 vaccines with the bivalent version for the primary series," but said, "more data is needed."

"Members disagree on whether children will need a primary series and favor the option for older adults and the immunocompromised to be vaccinated twice a year," Pharma Intelligence reported, but added that the transition, which requires FDA approval, "appears imminent."

ACIP members also could not come to a definitive agreement as to whether children should first be administered the primary series of COVID-19 vaccines prior to receiving the bivalent boosters, and said there isn't sufficient data to recommend more than one shot annually for older adults and the immunocompromised.

Dr. Sara Oliver, a pediatric infectious disease physician who leads the ACIP's vaccine work group, noted that most children ages 6 months to 4 years remain unvaccinated, and overall, the uptake of boosters is low.

Nass said the data on children and COVID-19 shots showed only 0.2% of children under age 2 and only 9% of preschoolers were administered a bivalent booster — "1 in 500 kids," while "more than 87% had some natural immunity."

"Parents seem to be watching and voting for the boosters with their feet," she said.

According to Nass, presenters at the ACIP meeting claimed the data "are not enough to conclude there is a stroke safety problem" and that strokes may be attributed to "random findings that are due to chance" or early COVID-19 vaccine adapters who "are simply more prone to stroke." Those who previously suffered strokes were excluded.

Nass said, "The issue of strokes related to the Pfizer vaccine was covered up, even though a [safety] signal persisted for about 10 weeks with a single arm."

The committee also downplayed other side effects, according to Nass, who wrote that cases of asthma were recorded after the bivalent vaccine was administered, but these cases were "judged unrelated," even though "asthma is a well-known adverse effect."

The committee did address myocarditis.

"The CDC data claimed there was more myocarditis from the Pfizer vaccine than the Moderna, which is the opposite of what about 10 countries who published their data have found. And about eight European countries banned the Moderna vaccine in young men."

Monkeypox scare rolls on, despite almost no cases

According to CNBC, ACIP members unanimously recommended the two-dose Jynneos mpox (monkeypox) vaccine "for adults at risk of mpox in potential future outbreaks."

"It's important to state that an mpox outbreak will be determined by public health authorities, and a single case may be considered an mpox outbreak at the discretion of the public health authority," Dr. Pablo Sanchez, head of the CDC committee's mpox workgroup, said.

The recommendation was made even though efficacy data is unclear. CNBC reported:

> "Studies found two doses of the Jynneos vaccine were at least 66% effective in preventing mpox, though other examinations found the shots' effectiveness was as high as 83%. The effectiveness of a single dose ranged from 36% to 86%, depending on the study.
>
> "It's still unclear how effective the vaccine is for people with weak immune systems, which is crucial given that 53% of people with mpox in the U.S. who disclosed their HIV status were positive."

Although "we learned that Monkeypox is over … with only 1 or 2 new cases per week in the US, CDC will not let it go," Nass wrote. "CDC has deputized other public health agencies to call a monkeypox outbreak for one case, if they want."

As a result, Nass said, "CDC can keep those vaccinations going" and can also "keep the EUA [Emergency Use Authorization] going," to protect the manufacturer, Bavarian Nordic, from lawsuits regarding its monkeypox vaccine, due to the legal shield the EUA provides.

ACIP "will meet again in June to discuss using the Jynneos vaccine for kids at risk of mpox in future outbreaks," CNBC reported, adding that the CDC is not currently recommending vaccination for those who have recovered from mpox, but that a study being conducted in the Democratic Republic of the Congo is examining the potential need for a booster dose.

Nass also highlighted the incidence of myocarditis associated with the Jynneos vaccine, stating that "in pre-licensure studies, there was a lot of myocarditis associated with this vaccine," and that at least five cases of myocarditis were reported from those who received the vaccine last year — and two deaths, although the deaths were attributed to drowning and cocaine toxicity.

Nass also noted that while the U.S. owns a stockpile of 30 million doses of two types of monkeypox/smallpox vaccines, they were, "for reasons never explained," not used during the "outbreak."

"The reason might have to do with the fact that, since it is licensed, it would have liability attached. By diluting it, an EUA was issued with no liability to the manufacturer or government," said Nass.

"Remember, the CDC did not even tell us how many people died, nor how many people had persistent symptoms or disability after their monkeypox infection," Nass said. "Because had they done so, it would have become obvious that the vaccine is utterly unnecessary as it is a brief, mild illness for most with no long-term sequelae," Nass wrote.

Vaccine injury victims 'brushed off'

Three COVID-19 vaccine injury victims spoke during the ACIP proceedings. On her live blog, Nass wrote:

> "Angie Bluford got two Moderna vaccines and is severely ill as a result, no longer able to work, though she was a kickboxer before the vaccines. She was still making spike [proteins] two years post-vaccination. She notes that CDC lied that a stroke signal was only found in one database.
>
> "Sara Ragonstan … is injured also after three Pfizer shots. She has vaccine-induced pericarditis and lots of quality of life. There have been no answers. She spent $25K of her own money to try and recover as regular drugs did not help. Very lonely journey and so little support from federal agencies.
>
> "Christina Labette: two Pfizer doses then stroke-like illness, cardiac and neuro[logical] symptoms, needs help with basic needs. Over $35K in medical bills and has over 30 new diagnoses. Mostly bedridden."

"You know we are real. What would you do if I was your family?" Labette told ACIP.

Dr. Grace Lee, ACIP chair, chief quality officer, director of quality at Stanford Medicine Children's Health and professor of pediatrics at Stanford University School of Medicine, "did not provide any courtesy to the three vaccine-injured" but instead "brushed them aside so the ACIP could vote to rubberstamp" current mpox policy, said Nass.

"This group is essentially a rubber stamp for predesignated decisions made by CDC," Nass wrote.

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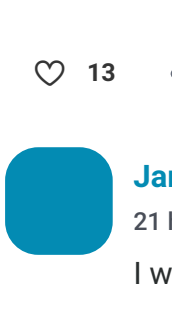

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Best Newest Oldest

James Wieck
21 hours ago
I will never trust the CDC, the FDA, or Big Pharma again.
32 0 Reply • Share ›

Nod ↪ James Wieck
18 hours ago
inequality = greed, envy, and violence.

moneypower rules

"you will own nothing, and be happy"
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Judith Marlowe ↪ Nod
7 hours ago
and we will refuse to comply.
3 0 Reply • Share ›

Judith Marlowe ↪ James Wieck
7 hours ago edited
Why limit it to these three agencies. Just turn your eyes to the W.H. and also the intelligence agencies.
3 0 Reply • Share ›

Heisenberg
20 hours ago
Between all their important meetings I guess they've failed to notice that nobody wants their vaccines anymore.
23 0 Reply • Share ›

Nod ↪ Heisenberg
17 hours ago
no worries, they are working on that at the W.H.O., giving that corrupt organization the right to rule you during a pandemic they declare. They will FORCE us all to take their garbage.

junkies. They want a world of junkies controlled not with "a trip", but with advanced bio-warfare.

No looking good, for the good guys.
3 0 Reply • Share ›

CAWS ↪ Nod
an hour ago
Everyone needs to bombard their Congress people to vote to prevent Biden from doing this by Executive order. It gives our sovereignty to UNELECTED officials with an AGENDA that is depopulation.
0 0 Reply • Share ›

Shazza
21 hours ago
Most of us knew years ago that this jab was not going to be good. Shame Doctors lack common sense these days.....they just do what they are told by big pharma.
21 0 Reply • Share ›

Nod ↪ Shazza
17 hours ago
"Most of us knew years ago "

So sorry, but this was my experience..
4 0 Reply • Share ›

gghoopman@gmail.com
21 hours ago
With what Americans' know about the CDC, WHO, WEF, NIH, ETC. why would anyone get another Poke? It's pretty clear the" One World Odor" doesn't want the Poor Nor Middleclass around any longer!
18 0 Reply • Share ›

Ricky Ricardo
20 hours ago
Rehashing the same old garbage; day in and day out! What's to discuss? Nothing...just say **NO** to the Big Pharma Criminals! Enough of this "Rocket Science"!
16 0 Reply • Share ›

gnt
21 hours ago
These meetings sound like a sham and a front to pretend there's some degree of public disclosure and accountability when in fact, like Dr. Nass said, the decisions and votes are already pre determined.
16 0 Reply • Share ›

dbj3
20 hours ago
And how many years has gone I to clinical studies??? Please, Do NOT fall for it again! 🙏🙏🙏
13 0 Reply • Share ›

Gary Brown
20 hours ago
SEP 3, 2022 Update on Myocarditis KIMBERLY MILHOAN, MD, FASA

Data supports a dose-response relationship to this cardiotoxin. Infection likely results in the smallest dose exposure to spike protein, as vaccination results in spike protein production for an as yet unknown period of time. Repeated vaccinations result in a greater incidence of damage. Vaccination with Moderna, which has about three times the mRNA than Pfizer, correlates with greater observed damage.

https://globalcovidsummit.o...
12 0 Reply • Share ›

Leslie Henderson
20 hours ago
This is just another govt /bigharma money laundering scheme, the govt is the only idiots buying these, with tax payer $ of course. The people don't want these vaccenes, or at least not as many seem too, unless? their just saying they won't take another shot, but will be compelled to do it anyhow? I sometimes wonder about that control?!
8 0 Reply • Share ›

Louke
19 hours ago
Being they're already ignoring adverse events and lack of efficacy, I guess that soon they'll do away with the clinical trials as well and just rubber stamp everything from the get go. Might as well, right?
5 0 Reply • Share ›

Truthie
20 hours ago
The switcheroo they are up to with keeping the EUA products which have a liability shield on the market, even when there are supposedly licensed alternatives that however are not available anywhere as they would be liable if they are not placed on a childhood vaxx schedule (or "tweaking" those alternatives just enough so they are different and, therefore, "need" a "new" EUA) is what everyone should be investigating and demanding action on. That alone should constitute fraud.
5 0 Reply • Share ›

Bonnie Gillmore
20 hours ago
Rare?
Do they realize how many millions of Americans have autoimmune disorders?
5 0 Reply • Share ›

annemat
13 hours ago
Just thinking that prior to covid I would obediently go and get my new vaccine with no questions asked. Thank you covid!
4 0 Reply • Share ›

Ruthiemae
18 hours ago
The ACIP member who brushed aside the three vaccine-injured people's testimonials about how the vaccines have ruined their lives just reflects what allopathic medicine always does: it exaggerates the benefits while downplaying the harmful effects of pharmaceutical products. People lives are ruined every day by vaccines and medicines that are not necessary, yet compassion and understanding from those committed to the pharmaceutical paradigm are nowhere to be found. They dismiss these people as collateral damage – damage that must be tolerated for "the greater good."

This notion of utilitarianism – that it's okay for some people to be hurt if more can (maybe) be helped -- is more like being in a war than striving for health. But for allopathic medicine, with its belief in germ theory (i.e., nature's germs are out to get us), this approach makes sense. It's okay to sacrifice a few "soldiers" to win the battle against the aggressor germs and viruses.

With true health, no one should ever have to be sacrificed (i.e., harmed by an intervention), which is why we need to move to a more individualized, intuitive, gentler, non-toxic, less brutal form of medicine. The current warlike approach is a really bad foundation on which to base health care. This Covid debacle is causing more and more people to critically examine this whole system, which will hopefully lead to the creation of new and better ways to stay healthy.
4 0 Reply • Share ›

ksj
17 hours ago
Our government at work once again!
3 0 Reply • Share ›

kibitzer3
12 hours ago

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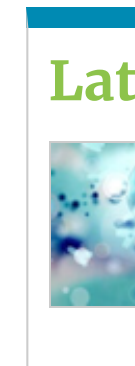
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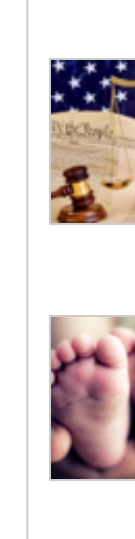
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